Exhibit 9

Johnson's[®] Baby Talcum Powder: A Comprehensive Review

Johnson & Johnson Consumer, Inc.
Current as of March 17, 2020

Confidentiality Statement

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EXECUTIVE SUMMARY

Johnson & Johnson first marketed talcum powder in 1894, and the formula has largely been unchanged since that time. The talc used in Johnson's Baby Powder contains greater than 99% talc and less than 1% fragrance. It meets pharmaceutical grade standards and does not contain asbestos. Careful selection of mines and rigorous testing from mine to manufacturer ensure the quality of the talc used in Johnson's Baby Powder. Clinical evidence, vigilant testing, and more than 40 years of research by independent medical experts and multiple regulatory authorities support that talc is safe for cosmetic use and does not cause cancer.

This briefing document summarizes the general use and safety of talc, and addresses how Johnson & Johnson ensures the quality of the talc used in Johnsons[®] Baby Powder. The document also summarizes relevant data related to talc toxicology, lung effects, data related to ovarian cancer, and post marketing safety.

1.1 Johnson & Johnson Baby Powder and Talc

Johnson's® Baby Powder meets or exceeds the standards for cosmetic and pharmaceutical grade talc around the world. Johnson & Johnson² continuously monitors its products and testing has repeatedly confirmed an absence of asbestos in its products.

- Talc adsorbs moisture to keep the skin dry and fresh, and its unique structure, composed of sheets which glide over each other under pressure, provides its anti-chaffing effects.
- For more than 40 years, there have been quality standards for cosmetic and pharmaceutical grade talc; under these standards, talc is required to be free of asbestos contamination.
- Johnson & Johnson sources talc from four carefully-selected mines that provide talc that does not contain asbestos.
- Additionally, Johnson & Johnson requires its talc suppliers to test talc for quality, prior to release to Johnson & Johnson, including specific testing for the presence

¹ Johnson's[®] Baby Powder is used throughout this document for simplicity and is intended to also refer to Shower to Shower® products prior to 2013 at which time they were divested by the Company.

² This document uses the name Johnson & Johnson to refer to past and present subsidiaries of Johnson & Johnson, a holding company, which were responsible for marketing Johnson's® Baby Powder domestically and abroad. This includes Johnson & Johnson Consumer Products, Inc., which became responsible for Johnson's Baby Powder in the United States in 1979.

DATA RELATED TO OVARIAN CANCER

9.1 **Background**

Ovarian cancer is a rare disease; it is estimated that 1.3% of women will be diagnosed with ovarian cancer during their lifetime [220]. Ovarian cancer is diagnosed predominantly in post-menopausal women; the median age of diagnosis of ovarian cancer is 63 years [220]. The National Cancer Institute (NCI) provided an evidencebased summary that included a summary of risk factors for ovarian cancer [82]. The following factors were considered to have adequate evidence of an increased risk of ovarian, fallopian tube, and primary peritoneal cancer: family history of ovarian cancer and inherited susceptibility (such as a BRCA1 or BRCA 2 mutation) to ovarian, fallopian tube, and primary peritoneal cancer; endometriosis; hormone replacement therapy; and obesity (increases in body mass index) and height (increases in height). The following factors were considered to have adequate evidence of a decreased risk of ovarian, fallopian tube, and primary peritoneal cancer: oral contraceptives, tubal ligation, multiparity, salpingectomy, breastfeeding, and risk-reducing bilateral salpingooophorectomy.

Epithelial ovarian cancer accounts for 90% of ovarian cancers, with germ cell and stromal tumors accounting for the majority of the remainder [221]. Epithelial ovarian cancer has been characterized by histologic type as serous, mucinous, endometroid, and clear cell [82]. More recently, epithelial ovarian cancers have been characterized as being either type I or type II tumors, with type I tumors being generally slow growing and including endometriosis-related tumors (endometroid, clear cell and seromucinous), lowgrade serous carcinomas, and mucinous carcinomas and malignant Brenner tumors In contrast, type II tumors are aggressive and include high-grade serous carcinomas, undifferentiated carcinomas, and primary peritoneal carcinomas [222]. It has been argued that these different histologic types (I and II) of epithelial ovarian cancer represent two different groups of disease [222]. This poses challenges for interpretation of etiologic data [82].

9.2 **Epidemiologic Studies of Talc Use and Ovarian Cancer**

A systematic review of the published literature was conducted to identify epidemiologic studies of talc use and ovarian cancer in humans. Databases reviewed included Proquest and PubMed and included epidemiologic studies written in English and published any time up to March 20, 2019. Search terms for outcomes included female reproductive organ cancers (ovarian, cervical, tubal (fallopian), endometrial, uterine, vaginal, and vulvar cancers). Search terms for methods included epidemiologic studies

(observational database, retrospective, prospective, case-control, cohort, meta-analysis, and systematic review).

The search identified 307 studies. Study abstracts were reviewed to identify relevant epidemiologic studies. If a determination concerning relevancy could not be made based on review of the abstract, the full-text article was obtained and reviewed.

While published after the March 20, 2019 literature cutoff date and thus not identified in the literature search, two additional studies, one meta-analysis by Taher et al published later in 2019 [89] and one pooled analysis by O'Brien et al published in 2020 [275] came to our attention and have also been included.

It is accepted that there is a hierarchy of human evidence by study design when evaluating the relationship of exposure to disease [223]. The hierarchy from top to bottom is as follows: randomized clinical trial, cohort study, case-control study, analyses of secular trends, case series, and case reports. The evidence by type of study is considered more convincing and if associations are found are more likely to be causal at the top of the hierarchy and decreases from top to bottom of the hierarchy. This hierarchy was considered throughout this review of epidemiologic data.

The sections that follow summarize results from studies concerning ovarian cancer from three prospective studies, 27 case-control studies, six meta-analyses, and 11 pooled case-control studies.

9.2.1 Prospective (Cohort) Studies

In studies with a prospective cohort design, subjects with and without the exposure of interest are followed for development of the disease of interest. In prospective studies, exposure is assessed at the time of enrollment into the study.

Three large prospective (cohort) studies (four publications) of talc use and ovarian cancer risk are summarized below. The three studies include the Nurses' Health Study (Gertig et al 2000 [225] with follow up by Gates et al 2010 [226]), the Women's Health Initiative-Observational Study (Houghton et al 2014 [227]), and the Sister Study (Gonzalez et al 2016 [228]). The Women's Health Initiative-Observational Study obtained and reported more generally on the use of powder while the Nurses' Health Study and the Sister Study obtained and reported specifically on the use of talc.

by route of exposure from use on the perineum, underwear, sanitary napkins, diaphragms or partner use.

Temporality of association was clearly met for the prospective cohort studies that found no association between perineal talc use and ovarian cancer. For the case-controls studies, there were questions about whether women who were cases may have been reporting on talc used after the diagnosis [264], because of a long time lag between diagnosis and interview. In order to address this potential weakness, some case-control studies asked respondents to report on talc use prior to the year before the diagnosis [273].

On balance, given the more than 47 years of research available on talc use and ovarian cancer, comprehensive consideration of all the available data supports that talc does not cause ovarian cancer. We note that these conclusions have also been confirmed by the CIR Expert Panel [21], in addition to independent comprehensive reviews by NCI Physician Desk Query (PDQ) [82] and US FDA [64], among others.